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EXAMINER

PREBILIC, PAUL B

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEROME ASIUS, HATEM FESSI, FRANCK GOUCHET,
BENEDICTE LAGLENNE and ELISABETH LAUGIER-LAGLENNE

Appeal 2009-003445
Application 10/809,349
Technology Center 3700

Decided: September 23, 2009

Before WILLIAM F. PATE III, STEFAN STAICOVICI, and
KEN B. BARRETT, Administrative *Patent Judges*.

WILLIAM F. PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL
STATEMENT OF CASE

This is an appeal from the final rejection of claims 10-19 and 23-27. Claims 1-9 have been canceled and claims 20-22 and 28-30 stand withdrawn from consideration. We have jurisdiction over the appeal under 35 U.S.C. §§ 134 and 6.

The claimed subject matter is directed to a reconstitutable product, which upon the addition of water becomes a bioresorbable, injectable implant composition. Upon reconstitution the composition includes microparticles and a hydrogel.

Claim 10, reproduced below, is further illustrative of the claimed subject matter.

10. A reconstitutable product, which upon the addition of water becomes a bioresorbable, injectable implant product, wherein said reconstitutable product comprises a freeze-dried composition of:

microparticles of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and

a hydrogel precursor consisting essentially of materials of non-animal origin, wherein said precursor forms a hydrogel upon the addition of water.

REFERENCES

The references of record relied upon by the examiner as evidence of obviousness are:

Sander	US 5,356,629	Oct. 18, 1994
Supersaxo	US 5,470,852	Nov. 28, 1995
Scopelianos	US 5,599,852	Feb. 04, 1997

REJECTIONS

Claims 10-19 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sander in view of Supersaxo.

Claims 24-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sander in view of Supersaxo, and further in view of Scopelianos.

OPINION

We have carefully reviewed the rejections on appeal in light of the arguments of the Appellants and the Examiner. As a result of this review, we have reached the conclusion that the Appellants have established that the Examiner erred in rejecting the pending claims under 35 U.S.C. § 103. Therefore, the rejections are reversed. Our reasons follow.

While the Appellants and the Examiner have expended much energy discussing the nature of gels, in our view, the key to this case is whether it would have been obvious to freeze dry Sander and whether Sander could be reconstitutable or injectable after reconstitution. See Brief 8:4-9; Reply 5:5-6:10. In our view, the Examiner's case of reconstitutability is based on conjecture, as the Sander patent does not disclose freeze drying, and, in fact, the Sander compositions are mixed directly before use. While we acknowledge that Supersaxo discloses freeze drying compositions with microparticles having the same composition as Appellants' claimed microparticles, Supersaxo does not disclose whether gels containing these microparticles having the same compositions as Appellants' hydrogels can be reconstituted as Appellants claim. Supersaxo is simply silent as to whether a composition similar to the Sander composition could be reconstituted to hydrogels as claimed by Appellants.

We note that the Examiner references column 3, lines 38-47 of Sander wherein, according to the Examiner, it is stated that the compositions of Sander can be wetted to make them more workable. Answer at 6. We do

not find the added “workability” in that passage, however, and even if that passage were as the Examiner has stated, it provides little evidence that the composition of Sander could be freeze dried and reconstituted to a hydrogel with microparticles therein. The Examiner also relies on an inherency argument. The argument is that since at least one substance in the Sander disclosure is the same as at least one gelling agent claimed by Appellant, the composition of Sander must necessarily be capable of being freeze dried and reconstitutable in a similar manner to Appellant’s claimed freeze-dried composition. “Under the principles of inherency, if the prior art *necessarily* functions in accordance with, or includes, the claims limitations, it anticipates.” *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed.Cir.2002). We are of the view that there is simply insufficient evidence in Sander and Supersaxo to support a finding that the Sander composition is *necessarily* reconstitutable if it were freeze dried.

Similar, for the reasons discussed above, we believe the prior art also fails to establish the injectability of the Sander composition either before or after it has been freeze dried as proposed by the Examiner. Appellants’ argument that the putty disclosed by Sander is not injectable is not seen as rebutted by the Examiner’s arguments of inherency for the reason given above with respect to reconstitution.

A touchstone of the Supreme Court’s holding concerning obviousness in *KSR Int’l. v. Teleflex, Inc.*, 550 U.S. 398 (2007) is predictability. The prior art methods or elements may be combined if one of ordinary skill would have found the results predictable. In our view there is simply insufficient disclosure concerning reconstitution of hydrogels in Sander and Supersaxo

Appeal 2009-003445
Application 10/809,349

to have provided one of ordinary skill with the requisite assurance of predictability to affirm a § 103 rejection based thereon.

We have also reviewed the disclosure of the Scopelianos patent but it does nothing to ameliorate the problem that we have found in the rejection based on Sander and Supersaxo. Accordingly, the rejections of all of the claims on appeal are reversed.

REVERSED

Vsh

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